



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,949	12/27/2001	Yusuf K. Hamied	33396-177202	7990

26694 7590 03/10/2005

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,949

Applicant(s)

HAMIED ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-19 is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/540,749.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-20 are pending in the application.

This action is in response to applicant's amendments dated December 7, 2004.

Claim 12 has been amended and claim 20 is newly added.

Response to Arguments

Applicant's arguments filed December 7, 2004 have been fully considered with the following elect:

1. With regards to the objection to the information disclosure statement filed October 8, 2003, it is noted that the reference is now present in the application, however, it is not in the English language and thus cannot be considered. The applicants indicated that the relevance of the reference is identified in the PCT search report, however, this was not seen by the Examiner.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claims 1-19 in the last office action, which is hereby **withdrawn**.
3. With regards to the 35 U.S.C. § 102(b) anticipation rejections of claims 1-11 in the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants' state that "it is axiomatic that, in order to anticipate a claim, a reference must contain, either expressly or inherently, each and every limitation of the claim. There is simply nothing in Chakrabarti that discloses the olanzapine polymorphs having x-ray diffraction patterns and infrared spectra described and claimed

Art Unit: 1624

in the present application. Furthermore, it is possible to have liquid pharmaceutical compositions that retain the crystalline form of a compound. For example, when the formulation is in form of suspension, it is possible for drug to retain its crystalline form. Further a gel can be in the form of suspension or as a solution. If the gel is in the form of suspension it is possible to retain the crystalline nature of the drug. Hence in general it is possible to formulate a liquid formulation containing polymorphs provided the liquid formulation is not in the form of solution." U.S. '382 teaches and claims a pharmaceutical compositions of the instant invention where 2-Methyl-10-(4-methyl-1-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine (olanzapine) is the active ingredient. Claims 1-11 are directed to a pharmaceutical composition comprising as an active ingredient at least one olanzapine polymorph selected from Form III olanzapine, Form IV olanzapine, Form V olanzapine, and salts and mixtures thereof. The definition of polymorph is such that a polymorph is a specific **crystalline form** of a compound that can crystallize in different forms. However, a pharmaceutical composition of a polymorphic form of olanzapine in a non-solid no longer possesses its crystalline characteristics and thus the x-ray diffraction patterns or infrared spectra. Furthermore, claims 1-11 are not limited to suspensions or gels, but any pharmaceutical composition.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by CHAKRABARTI et al., U.S. 5,229,382, for reasons of record and stated above.

Claim Objections

4. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

5. Claims 12-19 are allowed. None of the prior art of record or a search in the pertinent art area teaches the method of use of the oloanzapine polymorphs as claimed herein.

Conclusion


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda L. Coleman
Primary Examiner Art Unit 1624
March 4, 2005